MEDICAL DESIGNS LLC

Surgical Instruments Designed by Doctors

213 Sunset Drive
Brandon, SD 57005
Phone: (605)351-4787
Fax: (605)335-1489
E-mail: axt1@worldnet.att.net

DEC 1 2 2000

K002970

510(k) Summary

1. **Submitter Information:**
Medical Designs, LLC
213 Sunset Drive
Brandon, South Dakota 57005
(605) 3376-6008
(605) 335-1489 Fax
e-mail: axt1@worldnet.att.net

Contact: Mr. Paul John Axt
Preparation Date: September 19, 2000

2. **Trade Name**:
Subdural Evacuating Port System (SEPS)

Common Name:
Subdural Fluid Drainage Kit

Classification Name:
Drainage Catheter/Central Nervous System (CNS) Fluid Shunt and Components

Classification:
The Subdural Evacuating Port System kit includes device components classified as Class II (21 CFR 882.5550, 21 CFR 882.4300, and 21 CFR 882.1620) and Class I (21 CFR 878.4680).

3. **Predicate Devices**:
Elekta (NMT Neurosciences) Subdural Drainage Catheter (K974726) used with Elekta (NMT Neurosciences) Suction Reservoir Kit (Item # 910-500);
Camino NeuroCare Micro Ventricular Bolt Pressure Monitoring Kit (K914735).

4. **Performance Standards**:
No applicable performance standards have been established by the FDA under Section 514 of the Food, Drug and Cosmetic Act.

5. **Device Description**:
The Subdural Evacuating Port System is intended for drainage of subdural fluid accumulations such as hygromas and liquid-state subdural hematomas without touching the brain. Utilizing a minimally invasive technique, the Subdural Evacuating Port System is designed to promote gradual brain re-expansion by creating a low homogeneous negative pressure throughout the subdural space as fluid is drained to an external reservoir.

The Subdural Evacuating Port System (SEPS) kit consists of a stainless steel evacuating port, stainless steel drill bit with safety stop collar, set screw and allen wrench, silicone tubing, a silicone suction reservoir bulb and flexible ruler.

The evacuating port is a 6mm outside diameter hollow tube, 4.5cm in length, with a pair of wings extending from the exterior surface to facilitate finger rotation insertion. The evacuating port has self-tapping threads on the proximal end and a series of annular barbs on the distal end. The 5.8mm drill bit is used to create a twist drill hole through the outer and inner tables of the patient's skull. After opening the dura with an electrocoagulator, the evacuating port is inserted into the opening of the skull with a manual twisting motion.

One end of the silicone tubing is attached to the barbed end of the evacuating port. The other end of the tubing is attached to the silicone suction reservoir bulb. A low homogeneous negative pressure ($\leq$17 inch H_2O) is applied allowing for external drainage of subdural fluid accumulations and the gradual decompression, re-expansion, and recovery of the brain.

6. **Intended Use**:
The Subdural Evacuating Port System is intended for drainage of subdural fluid accumulations such as hygromas and chronic or subdural hematomas to an external suction reservoir.

The Subdural Evacuating Port System is contraindicated for patients with acute subdural hematomas and is not designed, sold, or intended for use except as indicated.

7. **Biocompatibility**:
The materials used to manufacture the SEPS kit components are identical to the materials used to manufacture the "equivalent" components found in the predicate device kits.

8. **Summary of Substantial Equivalence**:
The Subdural Evacuating Port System (SEPS) has the same intended use as the Elekta (NMT Neurosciences) Subdural Drainage Catheter Kit / Elekta Suction Reservoir Kit.

The Subdural Evacuating Port System is comprised of components that are similar in design, material composition, and method of use to components found in the Elekta (NMT Neurosciences) and the Camino NeuroCare predicate device kits and does not raise any new issues relating to the safety or effectiveness of its intended use.

9. **Performance Testing**:
The Subdural Evacuating Port System was evaluated on a limited number of human subjects presenting with subacute and chronic subdural hematomas. On average, fluid accumulation size reductions ranged from 38% to 100% with a mean reduction in size of 82.8%. 64% of all patients experienced complete resolution. In all cases, the Subdural Evacuating Port System drained subdural fluids in a safe and effective manner without complications or adverse events.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 12 2000

Mr. Paul John Axt
Director of Research and Product Development
Medical Designs, LLC
213 Sunset Drive
Brandon, South Dakota 57005

Re: K002970
Trade Name: Subdural Evacuating Port System
Regulatory Class: II
Product Code: JXG
Dated: September 19, 2000
Received: September 22, 2000

Dear Mr. Axt:

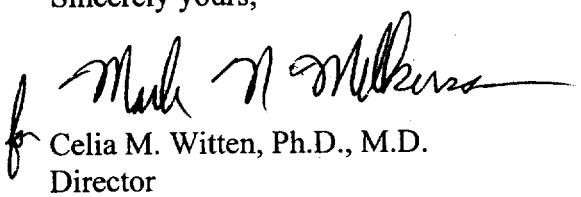
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K002970

Statement of Indications for Use

"The Subdural Evacuating Port System is intended for drainage of subdural fluid accumulations such as hygromas and chronic or subacute hematomas to an external suction reservoir."

"The Subdural Evacuating Port System is contraindicated for patients with acute subdural hematomas, and is not designed, sold, or intended for use except as indicated."

for Mark N Melkerson

(Division Sign-Off)
Division of General Restorative Devices

510(k) Number K002970